Testimony
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Combating the Flu: Keeping Seniors Alive

Statement of

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Good Morning, Mr. Chairman and Members of the Committee. I am Dr. Stephen Ostroff, Deputy Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied today by Dr. Lance Rodewald, Director, Immunization Services Division of CDC's National Immunization Program. Thank you for inviting us to provide information on the upcoming influenza season, especially with regard to older Americans. CDC has been working hard for many years to raise awareness of the need for influenza vaccinations, and we appreciate your interest in and support for preparedness for this and future influenza seasons.

Introduction

You may have heard of the recent CDC study published in the Journal of the American Medical Association showing new estimates that more than 200,000 respiratory and circulatory hospitalizations and 36,000 deaths are associated with influenza each year in the United States, substantially more than previous estimates. The report notes that the aging of our population is an important contributor to the increasing numbers of influenza-associated hospitalizations and deaths. Based on US census estimates, the numbers of very elderly people (85 years and older) in the United States will continue to increase. Consequently, the numbers of influenza-associated hospitalizations and deaths will also likely increase over time unless we take action to strengthen our vaccination efforts. According to the National Health Interview Survey, only about 64 percent of those over age 65 were immunized for influenza in 2002. Although this is a higher percentage of influenza vaccination than for other targeted groups, it is still insufficient. Additional efforts are needed to ensure that current recommendations for influenza vaccination for all high-risk individuals, those who

live in households with high-risk individuals and health care workers that care for these persons are fully implemented. Efforts to vaccinate older Americans and their contacts annually must continue to be a priority for immunization programs.

The elderly population is steadily increasing worldwide due to improved healthcare practices and advances in medical science. However, illnesses caused by a number of infectious diseases are still high when compared with that of younger individuals. This is due to a decline in immune function, which affects both the ability to resist infectious diseases and the ability to generate protective immune responses following vaccination. As a result, the incidence of severe respiratory disease, not only due to influenza but also due to respiratory syncytial virus (RSV) and pneumococcal pneumonia, increases in the elderly.

Surveillance and Vaccine Strain Selection

Protecting individuals who are at greatest risk of serious complications from influenza through vaccination is the primary strategy for preventing severe complications from the disease, including associated deaths. CDC, in collaboration with WHO, FDA, and regulatory agencies from Australia, Japan, and the United Kingdom, examines data to determine what, if any, vaccine strain changes should occur each year to keep the vaccine well matched with the currently circulating influenza strains. We know the vaccine works best when the vaccine strains are closely matched to the strains that circulate. As part of the vaccine strain selection process each year, CDC studies the immune response of vaccinated volunteers to determine how well the current vaccine protects against the currently circulating influenza viruses. Responses in young children, healthy adults, and older persons are examined to help ensure that the vaccine

strains selected are the best overall choice after taking all age groups into consideration.

Although we cannot predict the timing or severity of the influenza season, we are constantly monitoring influenza viruses worldwide for changes that might indicate the need to change the vaccine strain. So far this season, very few influenza viruses have been isolated from U.S. patients. However, the majority of strains that CDC has characterized are well matched to the vaccine that has been produced for the coming season.

Influenza Vaccine Supply: Past, Present and Future

U.S.-licensed influenza vaccine is produced by three manufacturers, two making inactivated vaccine and one making a live attenuated vaccine delivered by nasal spray. All vaccine is produced, and the vast majority distributed and administered, by the private sector. Because of the time required to manufacture vaccine and the need to obtain adequate supplies of embryonated eggs in which influenza virus is grown for vaccine production, manufacturers must predict demand and decide on the number of vaccine doses to produce 6 to 9 months before the onset of the influenza season.

Production of vaccine for the 2003-2004 influenza season was based on the previous year's demand. During the 2002-2003 influenza season, supply exceeded demand by approximately 12 million doses, which were not sold. Therefore, the next year manufacturers produced about 83 million doses of the inactivated vaccine, as well as about 4 million doses of the live attenuated vaccine, for a total of approximately 87 million vaccine doses. Unfortunately,

last year the demand for influenza vaccine in the United States exceeded what had been experienced in previous influenza seasons. We believe this shortage resulted from the early onset of the influenza season, which occurred during the months that vaccination usually takes place, and the widespread media reports of influenza-caused deaths among children.

Based on information from influenza vaccine manufacturers, 100 million doses of influenza vaccine will be available to Americans in 2004. This record number of doses should be an adequate supply for the upcoming season. However, demand is always difficult to gauge, and this year influenza vaccination is being recommended for the first time for all children 6 months to 23 months of age by CDC, the American Academy of Pediatrics, and the American Academy of Family Physicians. In an attempt to foresee a shortage, CDC conducts weekly calls with influenza vaccine manufacturers to monitor vaccine supply throughout the influenza season.

In addition, in August, one of the two manufacturers of inactivated influenza vaccine announced that some vaccine lots, amounting to approximately 2 million doses of vaccine, were contaminated and cannot be used. The manufacturer is retesting the remaining lots of vaccine for sterility, and this additional testing will introduce a delay in the release their vaccine by approximately one month.

On the plus side, CDC has contracted for the first time ever for a stockpile of inactivated influenza vaccine (4.5 million doses) for the upcoming season. This vaccine will become available early in December 2004. This stockpile should work to cushion any concerns about potential shortfalls.

DHHS is currently working on long-range strategies to improve future influenza vaccine supplies. The current egg-based system used to produce licensed influenza vaccines – despite being reliable for more than 50 years – can be improved. Challenges to the current system include: 1) a lengthy manufacturing process; 2) the need to select which virus strains will be in the vaccine at least six months in advance of the influenza season; and 3) the need to produce 100 million plus doses of a new influenza vaccine each year, the amount needed to vaccinate all at risk people. The current production techniques cannot be scaled up rapidly enough to provide additional doses of vaccine if demand outpaces supply in a regular influenza season. Despite these challenges, egg based vaccines will continue to play an important role in the supply of influenza vaccines. To address the issues presented by current technology, DHHS is encouraging the development and U.S. licensure of influenza vaccines produced with new technology, including the development of cell culture-based vaccines. Resources have been made available in the FY 2004 budget, and requested in the FY 2005 budget, for this important activity.

Influenza Vaccine Recommendations and Improved Vaccine Coverage

Each year, CDC works with the Advisory Committee on Immunization Practices (ACIP) to review and update influenza vaccination recommendations. Relevant highlights of these recommendations include annual influenza vaccinations for all individuals 50 years of age and older, for individuals with medical indications including chronic diseases, such as cardiovascular disease, asthma, diabetes, and immunosuppression whether caused by medication or disease regardless of age, as well as for all persons in long term care facilities. Children between 6

and 23 months of age and close contacts of high-risk individuals should also get vaccinated.

Workers in certain occupations, who are likely to transmit influenza to others, should be vaccinated. This is especially true of health care providers. According to the National Health Interview Survey for Health Care Workers, only 38 percent of health care providers in this country receive influenza vaccine annually.

These annual ACIP recommendations are published before each influenza season so that providers can become familiar with them and have time to implement any recommended changes. Through our educational efforts for providers and the public, we are stimulating increased demand for vaccine. To achieve our Healthy People 2010 targets of vaccinating 90 percent of adults 65 years and older and 60 percent of high-risk adults ages 18 to 64, we will need to increase these efforts and address other barriers to vaccination. CDC and its partners are working in many ways to improve influenza vaccine uptake.

1. CDC has continued its collaboration with the Centers for Medicare and Medicaid Services (CMS) to encourage and promote “standing orders” to improve influenza and pneumococcal vaccination levels in nursing homes and other healthcare facilities throughout the country. A standing order enables a facility to provide these vaccinations by appropriately qualified personnel without an individual prescription. In 2002, CDC and CMS completed a three year program to promote standing orders for Medicare patients in nursing homes. Initial data showed that standing orders are both more effective and more cost-effective than other methods for

increasing immunization coverage against influenza and invasive pneumococcal disease among nursing home residents. Based on the success of this work and recommendations from ACIP, CDC worked with CMS to change Medicare's regulatory structure to encourage the use of standing orders for flu and pneumococcal vaccines in nursing homes, home health agencies and hospitals.

2. CDC and the American Medical Association have co-sponsored the annual National Influenza Vaccine Summit for the past four years. The Summit includes over 90 partners and stakeholder organizations working together year-round to address the challenges associated with production, distribution and administration of influenza vaccine. Both the National Council on Aging and the American Association of Retired People has attended Summit meetings.
3. The Department of Health and Human Services (HHS) has made the elimination of racial and ethnic disparities in influenza and pneumoccocal vaccination coverage for people 65 years of age and older a priority. To address these disparities and to assist in reaching the 2010 national health goal of 90 percent influenza and pneumococcal vaccination rates among persons 65 years of age and older, CDC and other federal partners launched the Racial and Ethnic Adult Disparities Immunization Initiative (READII) in July 2002. The five READII demonstration sites have developed partnerships with public health professionals, medical providers and community organizations to develop and implement community-based interventions and innovative approaches to increasing immunization levels.

4. The SPARC initiative (Sickness Prevention Achieved through Regional Collaboration), established by the Berkshire Taconic Community Foundation in 1994, represents a collaboration of 75 organizations and businesses with an interest in disease prevention in a four-county region at the junction of Connecticut, Massachusetts, and New York (regional population: 636,000). SPARC has been working since 1995 to increase the use of influenza vaccination among persons aged greater than or equal to 65 years in each of the four counties through outreach and marketing campaigns. To promote pneumococcal vaccination, in 1997, SPARC's collaborators in two counties offered pneumococcal vaccination along with influenza vaccination, which more than doubled the prevalence of pneumococcal vaccination with only a modest increase in resources.
5. Beginning in 2001, CDC requested that states develop contingency plans in the event of an influenza vaccine shortage and provided written guidelines to assist them in planning. Should a shortage of influenza vaccine occur, CDC has plans for recommending tiered vaccination. The recommendations would be for providers to vaccinate high risk patients, which includes seniors, on a priority basis.
6. During the 2003-2004 influenza season, the American Lung Association (ALA) implemented a web-based directory of influenza vaccination clinics throughout the nation. There were a record-setting 150 million hits to the Flu Shot Directory during October and November, 2003. The ALA hopes to have even more participation during the 2004-2005 influenza season.
7. To prepare for this season the National Foundation for Infectious Diseases released a call to action to address low influenza vaccination coverage among health care professionals.

Communications for the 2004-2005 Influenza Season

CDC begins its annual national public-education campaign to promote the benefits of influenza vaccine and the most current influenza vaccination recommendations prior to the influenza season. Partnerships with health departments, medical societies, social service organizations and the private sector are important elements in the influenza communication efforts. Those aged 50 and older are a key target of the public education campaign. This season CDC is promoting four key messages to providers and the public:

- Influenza is a serious disease;
- Getting vaccinated every year is your best protection;
- Your vaccination helps protect others;
- October and November are the best months to get vaccinated.

Based on formative research, printed materials have been developed in both English and Spanish and made available on the CDC website. Many of these materials target seniors and use images and messages that resonate with this audience. A national media campaign, consisting of press conferences, teleconferences, news releases (video, audio and print), and radio advertisements, was launched this month for the upcoming season.

CDC takes steps to communicate issues regarding influenza to all possible audiences. We have a proactive campaign to keep health care providers and states informed as the season progresses through the dissemination of a series of CDC Health Updates and articles in CDC's weekly publication, Morbidity and Mortality Weekly Report (MMWR). These publications provide updates on U.S. influenza activity and address issues such as the importance of timely

vaccination, with priority placed on vaccinating persons at high risk for complications from influenza. They also provide guidelines for infection control and use of antiviral drugs.

Preparedness for 2004-2005 Influenza Season

Domestic influenza surveillance will be augmented this season with two new components: surveillance for pediatric hospitalizations and pediatric mortality reporting. In addition, we are expanding our capacity to identify new strains of influenza viruses more rapidly and evaluating vaccine effectiveness annually using prospective study methods so that reliable information is available on the match of the vaccine to current circulating strains.

While domestic and international health are inextricably linked, the fulfillment of CDC's domestic mission – to protect the health of the U.S. population – requires increased global awareness and collaborations with global partners. To that end, HHS and CDC recently undertook an initiative to build capacity for influenza surveillance in Asia. By expanding international surveillance networks and sharing of influenza virus isolates through the World Health Organization (WHO) surveillance network, we will increase our ability to detect new variants earlier, and thus generate more timely data with which to make vaccine decisions. At the same time, we will have the added benefit of early warnings of new viruses with pandemic potential or other infectious diseases. The investment has already proven fruitful as the surveillance network created for influenza played a key role in detecting and characterizing the spread of SARS.

Influenza Pandemic Planning

While preparing for the upcoming season, the possibility of an influenza pandemic must also be considered. The National Vaccine Program Office (NVPO) in the Department of Health and Human Services has responsibility for coordinating and ensuring collaboration among the many federal agencies involved in vaccine and immunization activities. Significant progress has been made in vaccinating America's seniors. More needs to be done. In August NVPO published the pandemic influenza preparedness and response plan for public comment in the Federal Register. This plan includes approaches for improving annual influenza disease control, including vaccine production, distribution, and administration.

Conclusion

Mr. Chairman, although the influenza season arrived earlier than usual last year, associated disease and death was on par with other recent years when influenza A(H3N2) viruses predominated. However, the impact on the health of Americans, especially seniors, remains far too high. Last season's media attention increased consumer awareness of the impact of this disease and demand for vaccine late in the influenza season. The challenges of last season and the recent report in JAMA concerning the morbidity and mortality caused by influenza during regular seasons highlights the urgency of improving the nation's capacity to respond to a catastrophic event such as an influenza pandemic.

To address the challenges we face, we need to be able to respond more rapidly than current vaccine production methods allow. In addition, we need to enhance our monitoring activities so we can detect virus variants earlier so they can be incorporated into annual vaccine formulations. We must continue to strengthen

our promotional efforts to educate the public about the importance of routine influenza immunization to create the demand to vaccinate high-risk individuals, alleviate surges in demand, and develop a consistent market so manufacturers can better gauge vaccine supply. We must convince our seniors and others at high risk for complications from influenza to get vaccinated annually. Our continuing collaboration with state and local public health partners, healthcare providers, and private sector partners will improve our nation's ability to plan and prepare for influenza.

Thank you again for holding this hearing on such an important public health issue. I encourage you, if you are in one of the groups recommended to be vaccinated, to get your own influenza vaccinations. Dr. Rodewald and I would be happy to respond to any questions you may have.